



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,293	12/07/2004	Anders Larsson	PU0246	4704

22840 7590 06/22/2007  
GE HEALTHCARE BIO-SCIENCES CORP.  
PATENT DEPARTMENT  
800 CENTENNIAL AVENUE  
PISCATAWAY, NJ 08855

EXAMINER
----------

ZEMEL, IRINA SOPJIA

ART UNIT	PAPER NUMBER
----------	--------------

1711

MAIL DATE	DELIVERY MODE
-----------	---------------

06/22/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/517,293	<b>Applicant(s)</b> LARSSON ET AL.	
	<b>Examiner</b> Irina S. Zemel	<b>Art Unit</b> 1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-29 is/are pending in the application.
- 4a) Of the above claim(s) 18-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12-7-2004</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Invention Group I in the reply filed on 4-27-2007 is acknowledged.

Claims 18-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for branched hydrophilic polyhydroxy-functional polymers (with the required DB) that are derived from sugar or sugar alcohols crosslinked with epichlorohydrin (as per combined claims 7 and 9), does not reasonably provide enablement for any polyhydroxyfunctional polymers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Case law holds that applicant's specification must be "commensurately enabling [regarding the scope of the claims]" *Ex parte Kung*, 17 USPQ2d 1545, 1547 (Bd. Pat. App. Inter. 1989) otherwise undue experimentation would be involved in determining how to practice and use applicant's invention. Although the statute itself does not use the phrase "undue experimentation", it has been interpreted to require that the claimed

Art Unit: 1711

invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation as stated in *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. Inter. 1986) and in *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Specifically, in *In re Wands* the Court set forth a non-exhaustive list of factors to be considered in determining whether undue experimentation would be involved in making and/or using the claimed invention. These factors include, but are not limited to : (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applying these factors to the claims of the instant application, it is noted that the specification provides no direction or working examples (cf. factors (f) and (g)) for any polymer other than epichlorohydrin crosslinked sugar. Thus, the only portions of the specification that describe the polymer recited in claims 1-16 and 29 is the second full paragraph on page 12 and illustrative examples and these paragraphs exemplify only epichlorohydrin crosslinked polysaccharides only not any other polymer. There is no guidance as to how obtain any other polymers with specified DB that can be attaches to the polymeric matrix at multiple points.

Furthermore, in view of the breadth of claim 1 (cf. factor (a)) which encompasses innumerable polyhydroxy functional polymers it is urged that the quantity of

Art Unit: 1711

experimentation (cf. factor (h)) involved in order to reach a usable embodiment would be great. In light of the above factors, it is concluded that undue experimentation would be involved to make and use the invention as presently claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The base claim 1 recites "each polymer has been tethered...", however, the same claim recites branched hydrophilic polyhydroxy functional polymers that include hyperbranched polymers. It is not clear which of those polymers are "tethered to the base matrix". It creates confusion how "each polymer" which is not branched is attached to the matrix at multiple points, and also what exactly is meant by "each polymer", which appears to refer to each polymer chain of the branched polymer.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 3897414 discloses compositions containing dextrans and Ficoll, and 330747 discloses branched polyhydroxyfunctional polymers identical to the polymers attached to the matrix as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irina S. Zemel whose telephone number is (571)272-0577. The examiner can normally be reached on Monday-Friday 9-5.

Art Unit: 1711

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571)272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Irina S. Zemel  
Primary Examiner  
Art Unit 1711



ISZ